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Predicting Charge-Times of Implantable Cardioverter Defibrillators

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Abstract—**A novel method of validation of the mathematical model for batteries that power Medtronic's Implantable Cardioverter Defibrillators (ICDs) is presented. In a conventional approach used in the past, the model has been validated against data collected in controlled laboratory conditions. To supplement this approach, we now validate the model against ICD performance data reported from devices used in the field for periods ranging from about five to seven years. The key model output is ICD "charge time" – the time required to charge a high voltage capacitor in preparation to deliver shock to the heart. This validation is carried out for five of Medtronic's ICD designs and very close agreement is obtained between model predictions and field data.**

I. BACKGROUND

MEDTRONIC has developed lithium primary batteries with silver vanadium oxide cathodes as power sources for implantable cardioverter defibrillators (ICD's).[1] The ICD effectively treats multiple disease states of the heart – for example, when the heart beats slower than normal it provides pacing with low energy pulses; when the heart beats faster than normal it provides more frequent low energy pulses. Most critically, the ICD treats ventricular fibrillation. Also known as sudden cardiac death, ventricular fibrillation is a generally fatal condition, characterized by rapid, erratic contraction of the heart resulting in little or no pumping of blood. Within seconds of detecting ventricular fibrillation, the ICD delivers a high-energy pulse (typically up to 35 J) to the heart to bring it back to normal rhythm. To deliver this life-saving therapy, the ICD battery charges a capacitor to the desired energy level in as short a time as possible, and the capacitor is subsequently discharged through the heart. Because prompt therapy is desirable, the capacitor charge-time, typically in the range of 5 to 15 s, is a key measure of device performance.

Our group has earlier developed a mathematical model to predict ICD charge-times over battery life.[1] The model has been validated for all of Medtronic's ICD battery designs under rigorous laboratory test conditions (*e.g.,* specific applied load and energy delivered during pulsing).[1] In this work, we conduct an independent validation of the model by comparing its charge-time predictions against data observed from ICDs functioning in the field.

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II. THE MODEL

The mathematical model developed for ICD batteries is described in detail in Ref. [1]. The model predicts the background voltage (V_b), the DC resistance (R_{DC}), and the charge-time (T_{charge}) as functions of delivered capacity (q_{del}) and time (t) since the device has been implanted. The equations used to predict the background voltage and DC resistance can be represented conceptually in the form of transfer functions:

$$V_b = V_b\left(q_{del}\right) \tag{1}$$

and

$$R_{DC} = R_{DC}\left(q_{del}, t\right) \tag{2}$$

The dependence of the DC resistance, not just on capacity, but also on time is an important feature that enables accurate model predictions, especially in the latter part of battery discharge.

Based on the quantities calculated above, the model calculates charge-time over the life of the ICD:

$$\begin{aligned} T_{charge} &= \left(\frac{R_{load}E}{V_b^2}\right)\left(1+\frac{R_{DC}}{R_{load}}\right)^2 \\ &= T_{charge}\left(q_{del}, t\right) \end{aligned} \tag{3}$$

where E is the energy delivered by the battery during the pulse and R_{load} is the resistance of the load under pulse.

For specified therapy energy, therapy frequency and load resistance, the model predicts charge-time as a function of delivered capacity and the time of use. These quantities are readily measurable under specified test conditions, when the charge-time predictions have been validated against data for all of Medtronic's ICD battery designs. For an exemplary design, Fig. 1 shows the close agreement between the predicted and observed charge-times of several years of

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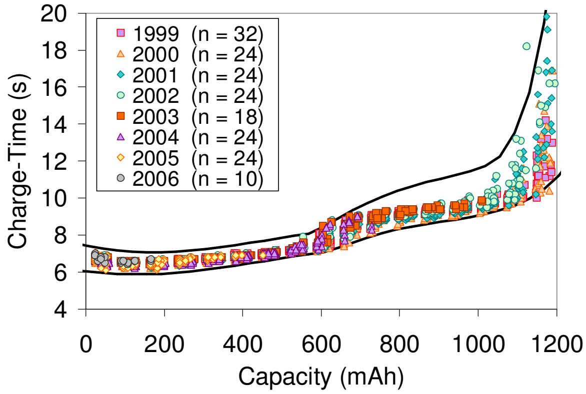

Fig. 1. Comparison between predicted and observed charge-times on a population of manufactured batteries under specified test conditions. The number of batteries and the year of manufacture are shown. The lines show the predicted range for the middle 99.8% of the population.

production of batteries. Monte-Carlo simulations based on typical variabilities in design parameters and operating conditions were used to predict the distribution of charge-times for a population of batteries.

III. Model Validation against Field Data

In this work, we validate the model against data obtained from ICD batteries serving patients in the field. These data are available in two forms – (a) cumulative device survival *vs.* time after implant, and (b) charge-time *vs.* time after implant. In our product performance report,[2] both data are available in the public domain for all of Medtronic's ICDs. The cumulative device survival and charge-times observed in the field for an exemplary design are shown in Fig. 2 (a) and (b), respectively.

The cumulative device survival curve shows the fraction of ICDs implanted that are still serving in the field at any time after implant. These data are collected at a population level by tracking devices that are explanted. In contrast, the charge-time data are obtained at the individual device level, and is collected when devices are interrogated via telemetry during regular clinical follow-ups. For a given ICD and battery design, there is a distribution in charge-times at any time after implant, because of the distribution in therapy requirements in the patient population. From Eq. (3), this means that at a given time after implant (t), there exists a distribution in delivered capacity (q_{del}), arising from distributions in therapy requirements, and resulting in a distribution in charge-time (T_{charge}). Since neither therapy requirements nor q_{del} directly is available from the field, it is not straightforward to make charge-time predictions with the model for validation against field data.

This problem is overcome by first expressing the delivered capacity as the product of time after implant and an average current drain (I_{avg}) experienced by the ICD battery:

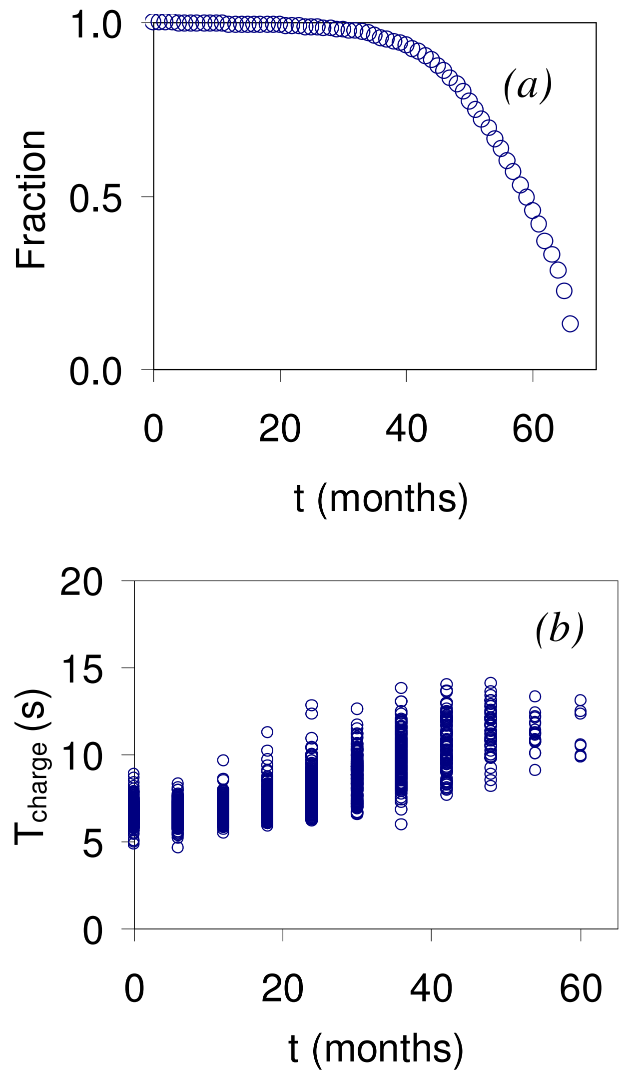

Fig. 2. Field data for an exemplary ICD design, adapted from the product performance report.[2] Part (a) shows cumulative device survival and part (b) shows charge-times observed versus time after implant.

$$q_{del} = I_{avg} t \tag{4}$$

Combining Eq. (3) and (4), we express the predicted charge-time as a function of the average current drain and time after implant

$$T_{charge} = T_{charge}\left(I_{avg}, t\right) \tag{5}$$

Second, we take a statistical approach to extract the distribution in the average current drain from the cumulative device survival curve. Inputting this distribution to the model in Eq. (5), and using Monte-Carlo simulations, we predict distributions in charge-times as functions of time

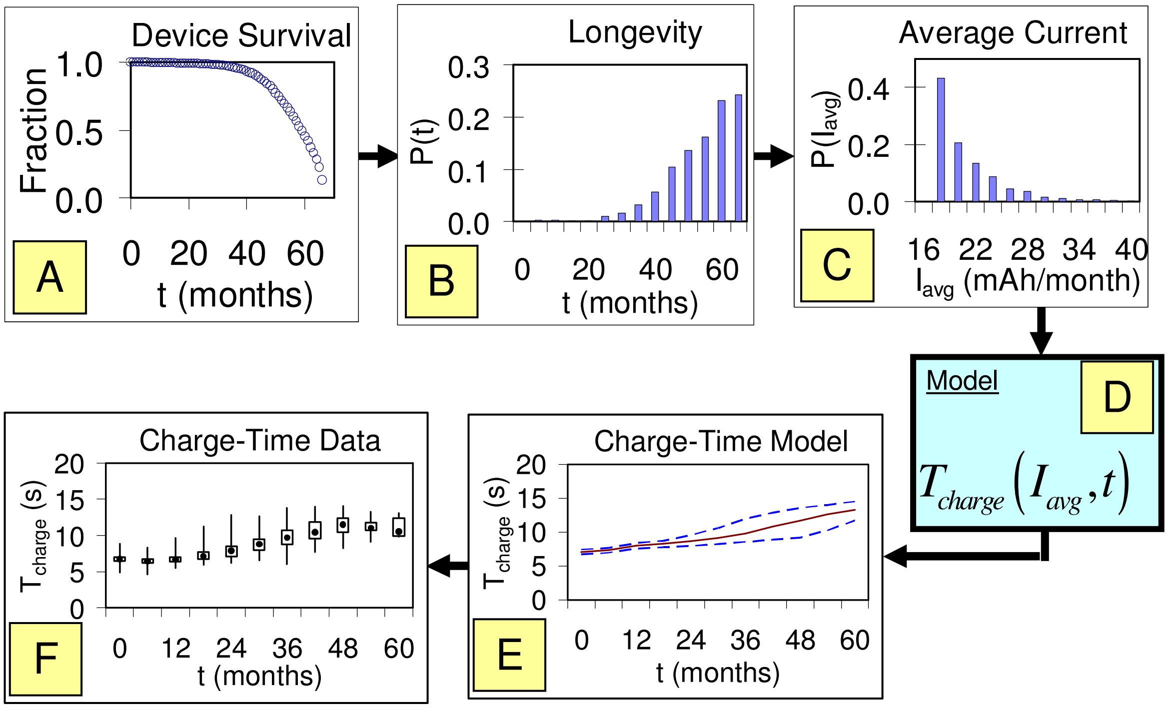

Fig. 3. Steps involved in model validation.

after implant. Thus, the charge-time predictions can be compared against field data on a population level.

For the exemplary design chosen, the steps involved in extracting the distribution in I_{avg}, and the subsequent validation process, are described using the block diagram of Fig. 3. We start from the device survival data of Fig. 2 as shown in block A. Differentiating this curve with respect to time (t) gives the distribution in longevities of the ICDs (block B). The battery capacity delivered up to explant (known *apriori* for any given battery design) is used to convert the longevity distribution into a distribution in average current drain:

$$I_{avg} = \frac{\text{capacity delivered up to explant}}{\text{longevity}} \qquad (6)$$

Here, we assume that all devices are explanted soon after their batteries reach the recommended point of explant. For the example ICD design considered here, explant is recommended when the battery's background voltage reaches 2.55 V.

The distribution in average current drain calculated from Eq. (6) is shown in block C. As mentioned earlier, a large distribution exists in patient therapy requirements and, consequently, in the average current drain experienced by the ICD batteries. Inputting the distribution in the average current drain to the model (block D), a distribution in charge-time is calculated for any time after implant. This is shown in block E, where the middle line shows the mean and the outer lines show where the middle 90% of the population is predicted to lie. This is then compared against field data on charge-time (block F). Block F is a box and whisker plot of the same field data as of Fig. 2 (b), showing the means (solid circles), the 25% and 75% quartiles (top and bottom edges of boxes), and the extremes of the population (ends of whiskers).

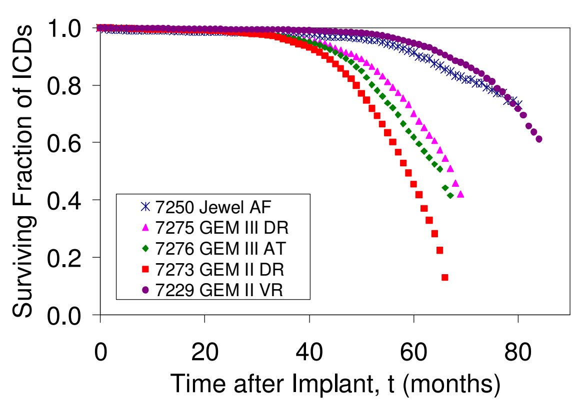

Fig. 4. Device survival data for five ICD designs, adapted from product performance report.[2]

The charge-time predictions of the model are compared against field data for five of Medtronic's ICD designs. As described above, the charge-time predictions are made for the five designs using their cumulative device survival curves shown in Fig. 4. The survival curves for the ICDs are very different from each other because of differences in battery sizes and current drains. Using the statistical software, @RISK™, as an add-in to MS Excel, the device survival curves are differentiated to obtain longevity distributions as well as to carry out the subsequent Monte-Carlo simulations. The distribution of longevities thus calculated for a population of ICDs is, in turn, converted into a current-drain distribution using Eq. (6). With this distribution as input to the model (Eq. (5)), Monte-Carlo simulations are conducted to generate charge-time distributions for a population ($\geq$ 1000) of ICD batteries.

Comparisons between predicted charge-times and field data are shown in Fig. 5. The excellent agreement observed provides an independent validation of the model, further confirming its reliability. Small deviations between predictions and data are observed, possibly arising from the assumption that all devices are explanted due to battery depletion. However, the deviations are such that the observed charge-times are generally less than the model predictions.

IV. CONCLUSION

A mathematical model of ICD battery performance, previously validated against data under specified test conditions in the lab, has now been validated for the first time against field data available in the public domain. The distinguishing feature of the present validation, as well as the greatest challenge, is that the average current drain of the ICD battery is unknown. This has been overcome by using the cumulative device survival data available from the field to calculate the average current drain distribution. Taking this as input, the distribution in charge-time *vs.* time after implant is calculated using the model. The predicted and observed charge-times from the field are compared for five ICD designs and close agreement is obtained. This independent field validation supplements earlier validations in the lab, and further confirms the reliability of the model.

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[2] Medtronic ICD Product Performance Report: http://www.medtronic.com/crm/ performance/icd/index.html.

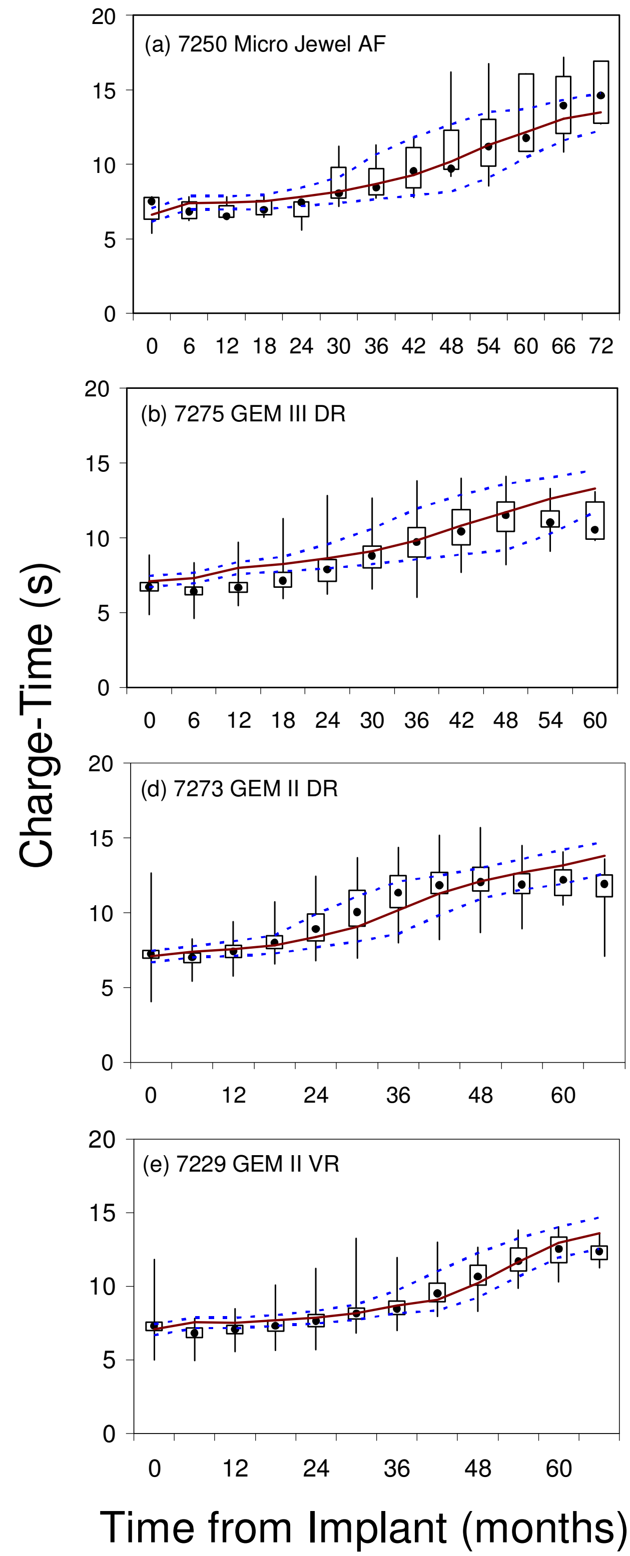

Fig. 5. Comparison between predicted and observed charge-time data from the field for five ICD designs, adapted from product performance report.[2] The top and bottom edges of the boxes show the 25% and 75% quartiles, the ends of the whiskers show the extremes, and the solid circles show the means of the data. The solid line shows the model mean and the dashed lines show the model bounds for the middle 90% population.